

AMENDMENT TO THE CLAIMS

This listing of claims will replace all prior versions of claims in the application.

Listing of Claims:

1. (Original) A peptide of least 9 amino acids in length derived from the tandem repeat domain of MUC1 and having the amino acid sequence SAP at its N-terminus.
2. (Currently Amended) The peptide of claim 1, wherein said peptide comprises essentially consisting of 10 to 25 amino acids of said tandem repeat domain of MUC1.
3. (Currently Amended) The peptide of claim 1 ~~or 2~~, which is a fragment of said tandem repeat domain, ~~preferably peptide SAP17 (SEQ ID NO: 11).~~
4. (Currently Amended) The peptide of claim 1 ~~any one of claims 1 to 3~~, which comprises an amino acid sequence of any one of SEQ ID NOS: 1 to 4 or 11, or variants thereof, wherein said variants comprise one or more amino acid additions, insertions, substitutions ~~and/or~~ deletions as compared to the sequence of any one of SEQ ID NOS: 1 to 4 or 11, and wherein the biological activity of said peptide is substantially equal to the

activity of the peptide comprising the unmodified amino acid sequence of any one of SEQ ID NOS: 1 to 4 or 11.

5. (Currently Amended) The peptide of claim 1 ~~one or more of claims 1 to 4~~, wherein one or more ~~of the~~ threonines or serines of the peptide are O-glycosylated.

6. (Currently Amended) The peptide of claim 5, having an amino acid sequence of any one of SEQ ID NOS: 1 to 4 or 11, wherein the amino acid is glycosylated at Thr 5 ~~and/or~~ 12.

7-24 (Cancelled)

25. (New) The peptide of claim 3, wherein said peptide is SAP17 (SEQ ID NO: 11).

26. (New) A nucleic acid encoding a peptide of claim 1.

27. (New) A method of producing a peptide having at least 9 amino acids derived from the tandem repeat domain of MUC1 and having the amino acid sequence SAP at its N-terminus, comprising the following steps:

- (a) providing a peptide comprising the tandem repeat domain of MUC1 or a part thereof, which part at least contains one repeating unit of said tandem repeat domain of MUC1;
- (b) contacting the peptide of (a) with an effective amount of cathepsin-L or a closely related enzyme hereof, thereby cleaving the peptide; and
- (c) isolating the fragments produced in (b).

28. (New) The method of claim 27, wherein the peptide provided in step (a) is natural MUC1 derived from human milk fat membranes, from human tumor ascites, or from human breast carcinoma cell lines or is represented by any one of SEQ ID NOS: 5, 6, 9, 10, or 12.

29. (New) The method of claim 27, wherein one or more of the amino acids of the peptide provided in step (a) is O-glycosylated, provided that the peptide is not glycosylated at the cleaving site of cathepsin-L.

30. (New) The method of claim 27, wherein one or more threonines or serines of the peptide fragment isolated in (c) are O-glycosylated.

31. (New) A peptide obtainable by the method of claim 27.

32. (New) A fusion molecule comprising the peptide of claim 31.

33. (New) An ex vivo-method of producing a population of autologous antigen presenting cells (APCs), which are capable of inducing effective immune responses against MUC1, comprising the steps of

- (a) providing autologous APCs from a tumor patient;
- (b) contacting the autologous APCs from the tumor patient with an effective amount of a peptide or fusion molecule comprising at least 9 amino acids of the tandem repeat domain of MUC1 and having the amino acid sequence SAP at its N-terminus, wherein said contacting is under conditions which allow endocytosis, processing, and MHC class II presentation of fragments of said peptide or fusion molecule by said APCs; and
- (c) isolating said peptide or fusion molecule fragment-presenting APCs for the purpose of immunotherapeutic application in the patient.

34. (New) The method of claim 33, wherein said peptide or fusion molecule comprises 10 to 25 amino acids of said tandem repeat domain of MUC1.

35. (New) The method of claim 33, wherein said peptide or fusion molecule is a

fragment of said tandem repeat domain.

36. (New) The method of claim 35, wherein said peptide or fusion molecule is SAP17 (SEQ ID NO: 11).

37. (New) The method of claim 33, wherein said peptide or fusion molecule comprises an amino acid sequence of any one of SEQ ID NOS: 1 to 4 or 11, or variants thereof, wherein said variants comprise one or more amino acid additions, insertions, substitutions or deletions as compared to the sequence of any one of SEQ ID NOS: 1 to 4 or 11, and wherein the biological activity of said peptide or fusion molecule is substantially equal to the activity of the peptide or fusion molecule comprising the unmodified amino acid sequence of any one of SEQ ID NOS: 1 to 4 or 11.

38. (New) The method of 33, wherein one or more threonines or serines of said peptide or fusion molecule are O-glycosylated.

39. (New) The method of claim 38, wherein said peptide or fusion molecule has an amino acid sequence of any one of SEQ ID NOS: 1 to 4 or 11, wherein the amino acid is glycosylated at Thr 5 or 12.

40. (New) The method of claim 33, wherein the peptides or fusion molecules in (b) are bound to ferric oxide beads.

41. (New) An ex vivo-method of producing genetically engineered antigen presenting cells (APCs), which are capable of inducing effective immune responses against MUC1, comprising the steps of

- (a) providing a nucleic acid encoding a peptide or fusion molecule comprising at least 9 amino acids of the tandem repeat domain of MUC1 and having the amino acid sequence SAP at its N-terminus,
- (b) transfecting the APCs with said nucleic acid, and
- (c) selecting APCs, which present said peptides in an MHC II restricted manner.

42. (New) The method of claim 41, wherein the nucleic acid of step (a) is provided in an expression vector.

43. (New) The method of claim 41, wherein said peptide comprises 10 to 25 amino acids of said tandem repeat domain of MUC1.

44. (New) The method of claim 41, wherein said peptide is a fragment of said tandem repeat domain.

45. (New) The method of claim 41, wherein said peptide is SAP17 (SEQ ID NO: 11).

46. (New) The method of claim 41, wherein said peptide comprises an amino acid sequence of any one of SEQ ID NOS: 1 to 4 or 11, or variants thereof, wherein said variants comprise one or more amino acid additions, insertions, substitutions or deletions as compared to the sequence of any one of SEQ ID NOS: 1 to 4 or 11, and wherein the biological activity of said peptide is substantially equal to the activity of the peptide comprising the unmodified amino acid sequence of any one of SEQ ID NOS: 1 to 4 or 11.

47. (New) The method of 41, wherein one or more threonines or serines of said peptide are O-glycosylated.

48. (New) The method of claim 47, wherein said peptide has an amino acid sequence of any one of SEQ ID NOS: 1 to 4 or 11, wherein the amino acid is glycosylated at Thr 5 or 12.

49. (New) An antigen presenting cell (APC) obtainable by the method of claim 41.

50. (New) The APC of claim 49, which is a dendritic cell or a B cell.

51. (New) A composition comprising a therapeutically effective amount of a peptide or fusion molecule comprising at least 9 amino acids of the tandem repeat domain of MUC1 and having the amino acid sequence SAP at its N-terminus or an antigen presenting cell comprising said peptide or fusion molecule and a pharmaceutically acceptable carrier.

52. (New) The composition of claim 51, wherein said peptide or fusion molecule comprises 10 to 25 amino acids of the tandem repeat domain of MUC1.

53. (New) The composition of claim 51, wherein said peptide or fusion molecule is a fragment of said tandem repeat domain.

54. (New) The composition of claim 53, wherein said peptide or fusion molecule is SAP17 (SEQ ID NO: 11).

55. (New) The composition of claim 51, wherein said peptide or fusion molecule comprises an amino acid sequence of any one of SEQ ID NOS: 1 to 4 or 11, or variants

thereof, wherein said variants comprise one or more amino acid additions, insertions, substitutions or deletions as compared to the sequence of any one of SEQ ID NOS: 1 to 4 or 11, and wherein the biological activity of said peptide or fusion molecule is substantially equal to the activity of the peptide or fusion molecule comprising the unmodified amino acid sequence of any one of SEQ ID NOS: 1 to 4 or 11.

56. (New) The composition of 51, wherein one or more threonines or serines of said peptide or fusion molecule are O-glycosylated.

57. (New) The composition of claim 56, wherein said peptide or fusion molecule has an amino acid sequence of any one of SEQ ID NOS: 1 to 4 or 11, wherein the amino acid is glycosylated at Thr 5 or 12.

58. (New) The composition of claim 51, which is a vaccine.

59. (New) A method of treating a patient suffering from a MUC1-positive carcinoma, said method comprising administering a composition comprising a peptide or fusion molecule comprising at least 9 amino acids of the tandem repeat domain of MUC1 and having the amino acid sequence SAP at its N-terminus or an antigen presenting cell comprising said peptide or fusion molecule, wherein said composition is administered to

said patient in an amount effective to induce an immune response against MUC1.

60. (New) The method of claim 59, wherein said peptide or fusion molecule comprises 10 to 25 amino acids of the tandem repeat domain of MUC1.

61. (New) The method of claim 59, wherein said peptide or fusion molecule is a fragment of said tandem repeat domain.

62. (New) The method of claim 61, wherein said peptide or fusion molecule is SAP17 (SEQ ID NO: 11).

63. (New) The method of claim 59, wherein said peptide or fusion molecule comprises an amino acid sequence of any one of SEQ ID NOS: 1 to 4 or 11, or variants thereof, wherein said variants comprise one or more amino acid additions, insertions, substitutions or deletions as compared to the sequence of any one of SEQ ID NOS: 1 to 4 or 11, and wherein the biological activity of said peptide or fusion molecule is substantially equal to the activity of the peptide or fusion molecule comprising the unmodified amino acid sequence of any one of SEQ ID NOS: 1 to 4 or 11.

64. (New) The method of 59, wherein one or more threonines or serines of said

peptide or fusion molecule are O-glycosylated.

65. (New) The method of claim 64, wherein said peptide or fusion molecule has an amino acid sequence of any one of SEQ ID NOS: 1 to 4 or 11, wherein the amino acid is glycosylated at Thr 5 or 12.

66. (New) The method of claim 59, wherein said composition is a vaccine.

67. (New) The method of claim 59, wherein the MUC1-positive carcinoma is a breast, a colorectal, a pancreatic or a gastric cancer.